

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION**

**J.B.D.L. Corp. d/b/a
BECKETT APOTHECARY, et al.,**

Plaintiffs,

v.

**WYETH-AYERST LABORATORIES, INC.,
et al.,**

Defendants.

Civil Action No. C-1-01-704

**Judge Sandra S. Beckwith
Magistrate Judge Timothy S. Hogan**

**CVS MERIDIAN, INC. AND RITE AID
CORP.,**

Plaintiffs,

v.

WYETH,

Defendant.

Civil Action No. C-1-03-781

Judge Sandra S. Beckwith

EXPERT REPORT OF DENNIS W. CARLTON

RESTRICTED HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

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quantities of drugs in anticipation of future price increases; after manufacturer list price increases, such purchases can be sold to retailers at prices that reflect the higher manufacturer list price.¹³ For example, Cardinal Health, Inc., a major wholesaler, explained in its 2003 10-K that it "historically invested capital in pharmaceutical inventory to take advantage of relevant market dynamics, including anticipated manufacturer price increases."¹⁴

14. Wholesalers sometimes are offered discounts by manufacturers based on volume or in exchange for prompt payment.¹⁵ However, because wholesalers' primary function is to fulfill customers' orders, wholesalers typically are not offered share-based rebates of the sort that manufacturers offer to MCOs and PBMs that can "shift share."

15. Some large retailers maintain their own warehouses and buy pharmaceuticals directly from manufacturers. Sales from manufacturers to retailers are typically referred to as "direct store deliveries." Wholesalers also offer "dock-to-dock" or "drop shipment" delivery service to retailers. In "dock-to-dock" transactions, wholesalers ship products from manufacturers to retailers' warehouses, in exchange for a fee, but do not take ownership of the drugs, and the drugs are not kept in the wholesaler's warehouses. A "drop shipment" involves a direct shipment from manufacturer to retailer (or retailer's warehouse), in which the order is placed and payment submitted through a wholesaler.¹⁶

(...continued)

(<http://aspe.hhs.gov/search/health/reports/drugstudy/index.htm>, accessed May 13, 2004).

13. See Declaration of John Trzaskalski, ¶12 (March 11, 2004).

14. Cardinal Health, Inc., 2003 10-K, at 10-11.

15. See, for example, <http://aspe.hhs.gov/health/reports/drugstudy/chap03.htm>, at 5, accessed May 13, 2004.

16. See "The Prescription Drug Marketing Act Report to Congress," Department of Health and Human Services, U.S. Food and Drug Administration, Attachment G at 1.3.1 (June, 2001).

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101. Finally, evidence suggests that wholesalers may sometimes benefit from list price increases and thus may not resist them. As I have discussed, wholesalers typically derive revenues from the practice of "speculative purchasing," which depends on list price increases. For example, Amerisource Bergen, a major drug wholesaler, reported in its 2001 10-K that its increase in inventory levels reflected "inventory purchased to take advantage of buy-side gross profit margin opportunities including manufacturer price increases and negotiated deals."¹¹⁷ The CEO of McKesson, a major drug wholesaler, has explained that there is "nobody in the channel that fights that price inflation as long as no one is disadvantaged in the process." He also stated that "we are happy to help price increases . . . as long as we are not disadvantaged."¹¹⁸

102. In summary, I conclude that:

- Wyeth's rebate contracts are procompetitive because they led to lower, not higher consumer prices; and
- Plaintiffs provide no evidence that Wyeth's rebate contracts led to higher prices paid by plaintiffs.

IX. CENESTIN'S SUCCESS HAS BEEN HAMPERED BY FACTORS OTHER THAN WYETH'S CONTRACTING PRACTICES

103. In this section of my report, I show that Cenestin's failure to reach Duramed's market share targets resulted from the product's limitations and Duramed's mistakes in marketing the product. The economic evidence shows that Cenestin was unsuccessful because:

- It provided no health benefits over Premarin and lacks Premarin's clinical history and indication for the prevention of osteoporosis;

117. Amerisource Bergen, 2001 10-K, at 20. Raymond Tiedemann of Wyeth testified that "not only did we never receive any complaints [from wholesalers about price increases], we were under the impression that the wholesalers were very happy with the price increases because their inventory automatically appreciated by the amount that we took our price increase and that was profit for the wholesalers." Deposition of Raymond W. Tiedemann at 242 (March 5, 2004).

118. See "RX Price Increases Continue, Wholesalers Say; Older Generics Have Largest," The Pink Sheet, March 24, 2003, vol. 65, no. 12, at 15, quoting McKesson CEO John Hammergren. Mr. Hammergren was discussing price increases on generic products.

EXHIBIT B

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EXPERT REPORT OF CHRISTOPHER M. JAMES

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D. Pharmaceutical Distribution and Pricing

16. Like other pharmaceutical products, Premarin and Cenestin are sold to consumers through a complex distribution system that includes wholesalers, retailers, insurers, and PBMs. Exhibit 1 illustrates the flow of products and payments among these parties. For this case, a key feature of the distribution system is that it involves multiple prices: the price typically paid by direct purchasers and a range of negotiated prices paid by health plans and PBMs. Plaintiffs focus on Wyeth's alleged failure to compete on list price, neglecting the competition that takes place on the net-of-rebate prices negotiated and paid by health plans and PBMs.

17. Wyeth, as a manufacturer, sells Premarin directly to wholesalers and to some retail pharmacies, hospitals, long-term care facilities and clinics. For the sake of simplicity, Exhibit 1 shows direct sales only to wholesalers and retail pharmacies.³⁰ Wyeth typically sells to direct purchasers at the list price (minus a 2% discount for prompt payment) and offers the same terms to most direct purchasers.³¹ Wholesalers typically earn only a slim margin on re-selling.³² Wholesalers can realize a higher margin when the list price of Premarin rises because Wyeth usually allowed them to purchase at the old, lower price for some period of time.³³ Wholesalers therefore have the opportunity to purchase at the lower

³⁰ Excluding sales to federal government entities and managed care organizations that are not part of this litigation, more than 90% of Wyeth's Premarin sales were to wholesalers or retail pharmacies in 1999-2003. Wyeth's Premarin Transaction Data.

³¹ See, e.g., Wyeth Invoice to Tepper Pharmaceuticals, M-0045 (two-percent discount paid for payments made within 30 days).

³² See U.S. Food and Drug Administration, "Profile of the Prescription Drug Wholesaling Industry: Examination of Entities Defining Supply and Demand in Drug Distribution," Final Report (Feb. 12, 2001) at 7 ("The wholesaler's markup to the manufacturer's price is modest, generally at 2 to 4 percent."), available at <http://www.fda.gov/oc/pdma/report2001/attachments/toc.html> (visited June 21, 2004).

³³ For example, when Wyeth increased prices on March 1, 2001, the price increase announcement (dated February 28) extended a "one-time buy-in offer to all customers who have purchased these products on a direct basis from July 2000 through December 2000. The special buy-in offer will allow you to purchase at the previous price, up to an average four week order for all products listed on your purchase order[.]" WYE

price and resell at a higher price. Wholesalers also engage in "speculative purchasing," purchasing higher-than-normal quantities in anticipation of an impending price increase.³⁴ This type of arbitrage can be quite profitable and is thus an important part of wholesalers' overall business model.³⁵ Retail pharmacies, whether they purchase directly or are supplied by wholesalers at the pharmacy acquisition price, sell Premarin to consumers. When the consumer is uninsured, the pharmacy charges her the "cash" price.³⁶

18. The parts of Exhibit 1 connected by dashed lines apply to purchasers insured under private health plans that directly reimburse pharmacies.³⁷ The PBM is shown in this illustration as a separate organization from the health plan. In this case, the PBM reimburses the pharmacy and the health plan reimburses the PBM. If the PBM function is not outsourced by the health plan, the second transaction is internal to the plan. In the remainder of this report, I will refer to a "managed care organization" ("MCO") as the combination of a health plan and a pharmacy benefit management function without regard to whether or not the function is outsourced.

086160. Buy-in opportunities are extended to direct purchasers who purchase on a list price basis as opposed to those who pay a discounted, contract price.

³⁴ See, e.g., Cardinal Health, 2003 10-K at 6 (Cardinal "historically invested capital in pharmaceutical inventory to take advantage of relevant market dynamics, including anticipated manufacturer price increase.").

³⁵ See, e.g., Tiedemann Depo. at 245-46 ("I believe [Wyeth] even had some wholesalers specifically requesting that [Wyeth] raise [its] pricing on certain days of the week based upon the pricing services issuing updates on Thursday of every week, and the wholesalers, wanting to maximize their profitability, had requested that we raise [Wyeth's] prices on a Tuesday, or a Wednesday of every week as opposed to a Thursday so that they didn't lose a week of those profits before they could raise their prices."); AmeriSource Bergen, 2001 10-K at 20 (AmeriSource Bergen's inventories reflected "inventory purchased to take advantage of buy-side gross profit margin opportunities including manufacturer price increases and negotiated deals.").

³⁶ This is also the price that would be paid by an insured consumer whose insurance plan reimbursed her rather than the pharmacy. These so-called "indemnity" insurance plans affect a very small share of purchases. See, e.g., Expert Report of David Gibson at 11 ("With indemnity insurance, the customer typically pays cash for the full cost of the prescription at the pharmacy and then files a claim for reimbursement from the insurer. Now most beneficiaries with private group coverage for prescription drugs have some form of managed drug benefit administered by a PBM or occasionally directly by an HMO or other underwriter.").

³⁷ State Medicaid programs directly reimburse pharmacies but have very different procedures and practices from the private health plans and PBMs depicted in this exhibit. Approximately 77% of ET sales during 2000 were made to persons covered by private health plans that directly reimburse pharmacies. TMS Health National Prescription Audit data; see also Leffler Report at ¶ 16 and note 28 (citing WYE 108012).

EXHIBIT C

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) Judge Sandra S. Beckwith
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EXPERT REPORT OF KENNETH W. SCHAFERMEYER, Ph.D

JULY 8, 2004

RESTRICTED HIGHLY CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER

Based on my knowledge of and experience in this industry and my review of the record, it is my opinion that:

1. When MCOs and PBMs chose not to add Cenestin to their formularies, these decisions were based on the lack of consumer and physician demand for Cenestin and Cenestin's deficiencies, including its lack of clinical advantages compared to existing formulary drugs.
2. Contrary to the plaintiffs' charges, a large percentage of formularies made Cenestin available at the same copayment as Premarin.
3. Prices for Premarin cannot be construed as "supra-competitive" (1) because pharmacies and wholesalers do not object to, and benefit from, price increases; and (2) even absent market-share rebate agreements, Wyeth would have no incentive to lower the price paid by pharmacies and wholesalers, an inelastic segment of the marketplace.
4. Pharmacies were not deprived of millions of dollars as alleged; in fact, they were not injured at all.

Part 3. Information Related to Drug Product Costs and Operation of Managed Care Prescription Programs

Since plaintiffs allege that Wyeth's actions "deprived plaintiffs and other direct purchasers of the ability to save millions of dollars,"^{5,6} it is important to know how pharmacies actually purchase drugs, how they are affected by price increases and how they are reimbursed for managed care prescriptions. The following information related to drug product costs and operation of managed care prescription programs clearly refutes the plaintiffs' allegations.

A. Pharmacies Purchase Inventory Either Directly from Manufacturers or From Wholesalers

Pharmacies' agreements with wholesalers for the purchase of pharmaceutical products were traditionally based on the average wholesale price (AWP). AWP is higher than the actual acquisition cost (AAC) that pharmacies pay for drug products. As shown in Equation 1, the difference between the average wholesale price and the pharmacy's actual acquisition cost is known as the earned discount.

(Equation 1) $AWP - AAC = \text{Earned Discount}$

⁵ Class Action Complaint, *JBDL Corp. v. Wyeth-Ayerst Laboratories, Inc.*

⁶ Complaint, *CVS Meridian, Inc. and Rite Aid Corp. v. Wyeth*

(Equation 7) $GM = Sales - AAC$

The GM can also be stated as a percentage of sales, as shown in Equation 8. For an individual product, GM% is also known as markup on retail.

(Equation 8) $GM\% = (Sales - COGS) \div Sales$

Another performance indicator is the level of inventory in either dollars or, more commonly, as a percentage of sales. Pharmacy managers try to keep inventory at about 8% of sales or less if possible. A third performance indicator is the inventory turnover rate (ITOR), which measures the number of times the average amount of inventory has been sold during the accounting period. (See Equation 9.) Managers try to increase ITOR to a point; if it is too high, though, it may result in excessive stockouts. The average pharmacy had an ITOR of approximately 10 times in 2002.⁷

(Equation 9) $ITOR = (COGS \div \text{Value of Average Inventory})$

Managers also try to maximize gross margin return on investment (GMROI), which is a product of the gross margin times the inventory turnover rate. (See Equation 10)

(Equation 10) $GMROI = GM \times ITOR$

A fifth measure to consider is the return on investment (ROI) in inventory. This can be expressed in either dollars or as a percentage. In terms of dollars, the inventory ROI is the same as the GM. Expressed as a percentage, inventory ROI is the gross margin (i.e., the return) divided by the amount invested in inventory. For an individual product, the inventory ROI percentage is also known as the markup on cost. (See Equations 11 and 12.) While managers want to increase both, a high ROI in dollars is more important than a high percentage ROI.

(Equation 11) $\text{Inventory ROI in \$} = Sales - COGS$

(Equation 12) $\% \text{ Inventory ROI} = GM \div COGS$

While pharmacy managers usually try to reduce inventory investment in order to increase the ITOR and percentage inventory ROI, there is another, seemingly contradictory strategy that can work very well. This strategy is known as "forward buying" or "anticipatory buying" – purchasing in anticipation of a price increase. This strategy works because the fixed-price payment pharmacies receive for drug product costs from MCOs is based on the AWP in effect at the time of the sale, regardless of the actual price paid by the pharmacy. In other words, the pharmacy purchases at the old price but gets reimbursed based on the new, higher price.

⁷ *NCPA-Pfizer Digest, 2003*

Pharmacy managers who want to take full advantage of a forward-buying strategy need access to sufficient cash and need to anticipate price increases. They can do this by observing trends of previous price increases (e.g., some companies increase prices once a year, others twice a year, etc.) Managers also learn from reading the news (e.g., they learn that a shutdown of manufacturing plant will likely result in shortages and price increases). Managers must also speculate that manufacturers' price increases will rise faster than the opportunity cost of not investing idle funds. With interest rates near historical lows and the Consumer Price Index for prescription drugs increasing much faster than the overall rate of inflation, this is a relatively safe bet.

Wholesalers have traditionally relied upon forward buying to purchase extra inventory in anticipation of a price increase. Although some wholesalers are now moving from a risk-based inventory speculation model to a fee-for-service business model,⁸ pharmacies are still able to benefit from speculative buying. In addition, wholesalers and pharmacies have taken advantage of "buy in" opportunities offered by pharmaceutical manufacturers, including Wyeth and Duramed, after the announcement of a price increase.⁹ The "buy-in" opportunities, like forward-buying, enable pharmacies to purchase product at the previous price, but get reimbursed at the new, higher price.

C. Pharmacies' Reactions to Price Increases

Pharmaceutical manufacturers' price increases result in higher AWP's and higher earned discounts, which increase the dollar amount of pharmacies' gross margins for managed care prescriptions. Price increases also promote forward purchasing, which can increase pharmacies' GM, GMROI and the inventory ROI.

Contrary to plaintiffs' allegations, pharmacies with a large percentage of managed care prescriptions actually benefit from prescription drug price increases. Thus, they may either support, or not oppose, manufacturers' price increases. I have seen no allegation by any of the plaintiffs or evidence that members of the class ever objected to a Premarin price increase.

Wholesalers and pharmacies are the most inelastic segment of the market. Therefore, there would be no incentive for Wyeth to reduce list price or decrease the rate of price increases. Indeed, Rite-Aid's and CVS' own expert appears to agree that Wyeth would be more likely to increase rebates to MCOs -- a much more elastic segment of the market -- than lower the list price.¹⁰

⁸ "Cardinal 'fee-for-service' model includes Rx product integrity payments," *The Pink Sheet*, Vol. 65, No. 43, October 27, 2003

⁹ AHP201873-75; AHP255046-50; AHP176864; SO-12357.

¹⁰ Leffler deposition, pages 221-222.

EXHIBIT D

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION AT CINCINNATI

J.B.D.L. Corp. d/b/a)	
BECKETT APOTHECARY, et al.,)	
Plaintiffs,)	CIVIL ACTION NO. C-1-01-704
v.)	
WYETH-AYERST LABORATORIES, INC.,)	Judge Sandra S. Beckwith
et al.,)	Magistrate Judge Timothy S. Hogan
Defendants.)	
<hr/>		
CVS MERIDIAN, INC. AND RITE AID)	
CORP.,)	CIVIL ACTION NO. C-1-03-781
Plaintiffs,)	
v.)	Judge Sandra S. Beckwith
WYETH,)	Magistrate Judge Timothy S. Hogan
Defendant.)	

EXPERT REPORT OF E.M. KOLASSA, Ph.D.

I. Qualifications and Assignment

I am an expert in the field of pharmaceutical marketing and economics and make this statement as an independent consultant. I am Managing Partner of Medical Marketing Economics, LLC, a consulting firm that specializes in research and consultation in the marketing and pricing of health care goods and services. I am also Adjunct Associate Professor of Pharmacy Administration at the University of Mississippi. I am former Associate Professor of Pharmacy Administration and Associate Professor of Marketing at the University of Mississippi, as well as Associate Director of the Center for Pharmaceutical Marketing and Management in the School of Pharmacy and Coordinator of the Pharmaceutical Marketing and Management Research Program in the Research Institute of Pharmaceutical Sciences. I hold a Bachelor of Arts Degree in Marketing and Economics (1978, Eastern Washington University), an MBA with concentration in Marketing and Decision Science (1980, Eastern Washington University), and a Doctor of Philosophy Degree in Pharmaceutical Marketing (1995, The University of Mississippi). A listing of my professional activities, publications, media work, consulting clients and expert testimony for the past four years is set forth in my current curriculum vitae attached as Exhibit A.

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Large pharmacy chains and mass merchandisers behave like wholesalers. In the model presented above, large pharmacy chains such as Walgreens, and mass-merchandisers such as Wal-Mart, purchase pharmaceutical and other products and warehouse them. This enables these large organizations to function as wholesalers to their stores. These distribution centers allow for the pharmacy chains and mass-merchandisers to reduce distribution costs and take advantage of the purchasing power they hold.

Table 1: Top Drug Chains, Mass Merchandisers, and Grocery Outlets³

Company	Number of stores with Pharmacy
CVS	4,191
Walgreens	3,520
Rite-Aid	3,497
Wal-Mart	2,977
Eckerd	2,641
Albertson's	2,421
Kroger	1,702
K-Mart	1,616
Safeway	1,250

B. How major wholesalers operate as direct purchasers

1. The margins on which wholesalers operate

The operating margins for the average drug wholesaler are exceptionally small. As traditional channel "middle-men", the wholesalers extract minimal dollars from the distribution chain. According to the Healthcare Distribution Management Association, formerly the Wholesale Druggists' Association, the average gross margin for drug wholesalers is 4.33% and their net profit after taxes is 0.73%.⁴

2. How wholesalers make money

To make money, in a distribution channel in which the margins are small, drug wholesalers employ a number of mechanisms. These include forward buying, anticipatory buying, cash discounts, bulk purchasing discounts, and repackaging goods.

a. Forward buying

Manufacturers often notify direct purchasers of upcoming price changes and allow the direct purchasers to buy inventory at the pre-adjustment price level. Wholesalers take advantage of such "forward buying" opportunities. Through this mechanism the wholesaler is able to purchase inventory at pre-price change prices and sell the inventory to their customers at post-change prices. Thus, wholesalers and other direct purchasers of

³ AHP444842-43.

⁴ Healthcare Distribution Management Association. Industry Fact Sheet. http://www.healthcaredistribution.org/resources/industry_fact.asp. Accessed 7-01-04.

pharmaceutical products do not object to price increases, but instead carefully monitor and rely on them for profit as part of their business model.

b. Anticipatory buying

In addition, pharmaceutical companies often institute their prices changes at regular intervals. This enables wholesalers to anticipate price changes and purchase inventory prior to the price change. Similar to forward buying, but without the consent of the manufacturer, this anticipatory buying practice (often referred to as “speculative purchasing”) enables wholesalers to purchase inventory prior to a price change and sell it to their customers at post-change prices.

c. Cash discounts

Traditionally, wholesalers and other direct purchasers are able to achieve a two percent discount off the price by paying the invoice within 30 days. Often times wholesalers, not accounting for forward buying practices, can purchase products at Wholesale Acquisition Cost (WAC) minus two percent and sell it to their customers at WAC plus two percent or more. This is a primary contributor to the wholesaler’s four percent gross margin.

d. Bulk purchasing discounts

Often, pharmaceutical manufacturers, such as Wyeth and others sell bulk packaged products at a discount per pill to their retail packages. For example, the AWP prices for Premarin 0.625 mg are \$104.25 for a bottle of 100, and \$1021.63 for a bottle of 1000. These AWP differences are \$0.02 per pill of Premarin 0.625 mg between the two bottles.

e. Repackaging goods

Discounts on bulk packaged pharmaceuticals enable wholesalers to repackage 1000 pill count bottles of pharmaceuticals into ten 100 pill count bottles in a repackaging facility. The higher the discount between package sizes the greater the incentive for the wholesaler to begin repackaging the product. These repackaged products have unique National Drug Code (NDC) number and are offered to pharmacies that the wholesalers contract with as a benefit of the relationship.

3. Recent consolidation and wholesaler competition

As the margins in the drug wholesaler industry have declined, the need for larger economies of scale to continue to achieve profit margins has grown, thus, larger and smaller wholesalers have consolidated, merged, or at least sought to merge their interests. In 1997, five major drug wholesalers accounted for nearly 79% of industry sales.⁵

⁵ Barbera P. The new trade marketplace and what it means to healthcare marketers. *Med Market Media*. 1999; 34(10):88-90, 94-100.

EXHIBIT E

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Magistrate Judge Timothy S. Hogan

FILED UNDER SEAL
PURSUANT TO PROTECTIVE ORDER

Declaration of Janusz A. Ordovery

RECEIVED

JUL 03 2002

KENNETH J. MURPHY, Clerk
CINCINNATI, OHIO

20. A PBM also negotiates with drug manufacturers for rebates that are based upon a drug's usage within the health plans serviced by the PBM.²⁹ These rebates have no effect on the transaction prices between the manufacturer and wholesaler, the wholesaler and the pharmacy, nor the pharmacy and the PBM. Rather, these rebates represent a separate deal between the PBM and the manufacturer, and only affect the PBM's (and accordingly the MCO/health plan's) net price for the drug. Again, rebates are generally earned based upon the prescriptions filled by the enrollees in the plans managed by the PBM, or on the PBM's demonstrated ability to move market share in favor of the manufacturer's drug.³⁰ This ability derives from the variety of measures a PBM can adopt to influence physician prescribing behavior and thereby increase demand for the manufacturer's drug.

21. With the exception of direct purchaser MCEs, direct purchasers generally have little or no ability to move market share. Direct purchasers face a "derived demand" for prescription drugs that wholly depends on the prescription practices of physicians. Admittedly, a particular wholesaler may be able to sell more of a given drug than its rival if it is willing to take a smaller mark-up on the drug. However, the total amount of the drug sold by all wholesalers (for example) is driven by how many prescriptions for a given drug are written by physicians, and not by the wholesaler's marketing and promotional efforts. Consequently, a direct purchaser will only purchase a drug in greater volumes if it expects to be able to sell the larger quantity to its customers. And that expectation will only arise as a result of an increase in patient demand, as determined by physician prescribing behavior.

22. The fact that only certain intermediate players in the distribution chain, principally MCEs, have the ability to move market share, has important implications for how a manufacturer will decide to adjust its pricing, if at all, in

²⁹ Kirking, Duane M., *et al.*, "Economics and Structure of the Generic Pharmaceutical Industry," *Journal of the American Pharmaceutical Association*, Vol. 41, No. 4, July/August 2001 ("Kirking") at p. 580.

³⁰ DHHS Study at Chapter 3, pp. 7-8.